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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,149	08/08/2003	Gerald E. McDonnell	MEDZ 2 01304	3426

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EXAMINER

HORNING, MICHELLE S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/637,149

Applicant(s)

MCDONNELL ET AL.

Examiner

Michelle Horning

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/21/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 14 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-13, 15-18 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to communications filed 5/18/2006 and 8/21/2006. The status of the claims is: claims 1-24 are pending, claims 1, 5-13, 15-18 and 22-24 are under current examination and claims 2-4, 14 and 19-21 are drawn to non-elected inventions. Applicant elected *o*-benzyl-*p*-chlorophenol and *o*-phenylphenol + brine. Of note, claims 2-4 do not read upon species *o*-benzyl-*p*-chlorophenol.

Applicant's election with traverse of Group I in the reply filed on 5/18/2006 is acknowledged. The traversal is on the ground(s) that search of all claims would not lead to a serious burden. This is not found persuasive because the inventions are distinct, requiring multiple database searches.

The requirement is still deemed proper and is therefore made FINAL.

Objection to Specification

The disclosure is objected to because of the following informalities: while the specification describes a Figure 6, Figure 6 has not been included. In total, there are only 5 figures.

Appropriate correction is required.

35 U.S.C. 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are drawn to *p*-chloro-*m*-xylanol; however, this compound cannot be found in the Merck Index. Of note, "xylanol" is in the Merck Index. Appropriate correction or further clarification regarding this compound is required.

35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 9, 18 and 22- 24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ernst and Race (1993). The limitations of the claim above are:

1. a method of treating a body which is contaminated with prions, comprising
2. contacting the body with a composition comprising a phenol to inactivate prions on the body; and
3. wherein the phenol concentration is about 10% ; and
4. wherein the phenol include *o*-benzyl-*p*-chlorophenol.

Ernst and Race teach a method in which the scrapie agent of brain homogenates is inactivated following treatment with LpH, or an aqueous phenolic disinfectant comprising *o*-benzyl-*p*-chlorophenol and *o*-phenylphenol (see page 196). Further, this reference teaches using a concentration of 90% of LpH (page 197) equating to 9%

phenolic derivative concentration (see 198 for conversion). Thus, the claims above are rejected.

35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ernst and Race (1993) in view of Werner et al (1983). The limitations of the above claims are:

1. a method of treating a body which is contaminated with prions, comprising
2. contacting the body with a composition comprising a phenol to inactivate prions on the body;
3. wherein the phenol concentration is up to 0.2M;

4. wherein the phenol has log Pc value of 2 to 6.5, 2-5 and at least 4.

The prior reference, Werner et al, disclose the physical properties of *o*-benzyl-*p*-chlorophenol, including partition coefficients at various interfaces (see Table 2). Ernst and Race teach a method in which varying concentrations of LpH are effective at removing detectable infectivity from the homogenate after 30 minutes. These concentrations include 90%, 81% and 9%. An overnight incubation at 0.9% LpH was also successful at removing all of the detectable infectivity (page 197). Although the above references do not specifically teach using a phenol concentration of 0.2M, it would have been obvious to one of ordinary skill in the art to vary the concentration of a disinfectant because concentration affects the amount of infectivity removed (see Figure 1). One would have been motivated to do so in order to optimize the conditions which would then lead to successful elimination all of the detectable infectivity. Given that elimination of infectivity or prions via phenol disinfectants taught by Ernst and Race, there would have been a reasonable expectation of success. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 10-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ernst and Race (1993) and Werner et al (1983), as applied to claims 1 and 5-9 above, and further in view of Cooper (1913) and Yamamoto et al (2001). The limitations of the above claims are:

1. a method of treating a body which is contaminated with prions, comprising

2. contacting the body with a composition comprising a phenol to inactivate prions on the body;
3. wherein the composition contains a soluble inorganic salt, more specifically, NaCl at a concentration of at least 2% by weight;
4. phenol includes either o-phenylphenol or o-benzyl-p-chlorophenol;
5. the phenol complexes with prions and precipitates; and
6. the phenol has minimal solubility;

Ernst and Race disclose a method in which a body contaminated with prions is treated with a composition comprising phenols as described above. Ernst and Race do not disclose prion precipitation or the use of inorganic salt in combination with the phenol composition. Cooper discloses the action of phenols in disinfectants and their precipitating effects on proteins, including their effects at various concentrations (see Introduction) and sodium chloride content (see 178, under Sodium Chloride). Further, Cooper teaches that "sodium chloride increase the germicidal and protein-precipitating action of phenol through increasing its solubility in proteins" (see Summary page 184). Yamamoto et al (2001) teaches that glycidol more effectively degrades scrapie prion protein in high salt conditions (see Figure 4). Given that Ernst and Race have already shown the effectiveness in reducing the infectivity of scrapie prions using phenols, it would have been obvious to one of ordinary skill in the art to use NaCl combined with phenol, both at varying concentrations. One would have been motivated to do in order to gain optimal conditions resulting in a more effective prion disinfectant. There would have been a reasonable amount of success given that the effects of high salt to

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phenol's protein precipitating powers and its effects to the prion protein is well known in the prior art. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. It is further noted that many references of the prior art teach the combination of phenol and salt in the compositions of disinfectants. See below for an example.

CONCLUSION

No claim is allowed.

Other references suggested for consideration are:

1. US Pat# 5185371
2. Polymenidou et al (2002) BMC Infectious Diseases 2: 23
3. Race and Raymond (2004) J. of Virology 78(4): 2164-2165.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

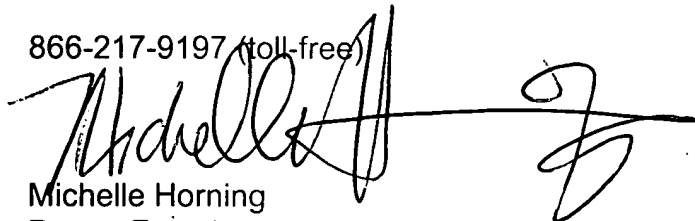
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished application is available through Private PAIR only. For more information

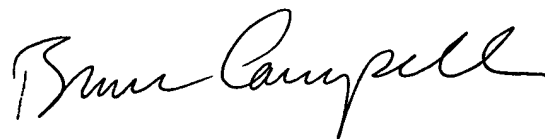
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about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at

866-217-9197 (toll-free)

A handwritten signature in black ink, appearing to read "Michelle Horning", with a long horizontal stroke extending to the right.

Michelle Horning
Patent Examiner

A handwritten signature in black ink, appearing to read "Bruce R. Campell", written in a cursive style.

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600